

**Appln. No.** : 10/035,389  
**Filed** : December 28, 2001

### **REMARKS**

In response to the Office Action mailed October 7, 2003, Applicant respectfully requests the Examiner to reconsider the above-captioned application. By this Amendment, Applicant has amended Claim 1 to clarify preferred features of the claimed invention and to further distinguish over the cited art. Claims 40-41 have been amended to provide proper antecedent basis. No new matter is added by this Amendment.

In response to the obviousness-type double patenting rejections based on a commonly owned issued patent, Applicant submits herewith a Terminal Disclaimer. Accordingly, Applicant believes that all of the Examiner's grounds for rejection have now been addressed and therefore respectfully requests that the Examiner pass the pending claims to allowance.

### **Priority Claims**

Applicant has deleted priority claims to U.S. Application Serial No. 08/933,816, filed September 19, 1997, now abandoned, and U.S. Application Serial No. 08/813,810, filed March 6, 1997, also now abandoned.

### **Claim Objections**

The Examiner objects to Claims 40 and 41 because "the occlusive device" of Claim 40 and the "inflatable balloon" of Claim 41 each lacks sufficient antecedent basis. Claims 40 and 41 have been amended such that Claim 40 now depends on Claim 39 and Claim 41 now depends on Claim 40. Accordingly, the objections to Claims 40 and 41 should be withdrawn.

### **Obviousness-Type Double Patenting Rejection**

The Examiner rejects Claims 9-11, 15-29, 31-44, 46 and 47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-59 of U.S. Patent No. 6,135,991 to Muni et al. The Examiner asserts that the rejected claims are not

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patentably distinct over Muni et al. because the rejected claims are merely broader in some aspects and add features in other aspects.

The Examiner also rejects Claims 12 and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 15 of U.S. Patent No. 6,135,991 to Muni et al. in view of U.S. Patent No. 5,092,841 to Spears. The Examiner asserts that Spears suggests using a thrombolytic agent for treating an arterial lesion.

Finally, the Examiner rejects Claim 14 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 15 of U.S. Patent No. 6,135,991 to Muni et al. in view of U.S. Patent No. 5,588,962 to Nicholas et al. The Examiner asserts that Nicholas et al. disclose a radioactive drug.

Applicant does not necessarily agree that Muni and/or Spears can properly be applied for an obviousness-type double patenting rejection. However, in order to expedite the allowance of the pending claims, Applicant submits herewith a Terminal Disclaimer. Applicant notes that U.S. Patent No. 6,135,991 to Muni et al. is commonly owned with the present application. Accordingly, Applicant respectfully requests withdrawal of all obviousness-type double patenting rejections.

**Rejection of Claims 1, 2, 4 and 36-41 under 35 U.S.C. § 102(b)**

The Examiner rejects Claims 1, 2, 4 and 36-41 as being anticipated by U.S. Patent No. 5,087,244 to Wolinsky et al. In particular, the Examiner asserts that Wolinsky et al. disclose a method of delivering fluid through the wall of a balloon 16 on a wire 10. Hence, the Examiner asserts that fluid contacts the occlusive device.

Applicant notes that Wolinsky et al. disclose a catheter and method for locally applying a chemical agent under sufficient pressure to cause the chemical agent to penetrate the localized tissue. (See abstract.) The catheter includes a thin-walled balloon 16 formed with a plurality of small holes 29. The balloon 16 is inflated in a body lumen and fluid passes through the holes 29 into the surrounding tissue.

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As amended, Applicant's independent Claim 1 recites a method for treating an intravascular occlusion comprising the step of delivering fluid containing an occlusion-treating drug into a blood vessel from a location proximal to an intravascular occlusive device. The drug is delivered such that at least a portion of the drug contacts the intravascular occlusive device. Applicant's recited method provides for localized delivery of the drug at the site of the occlusion.

Wolinsky et al. fail to teach or suggest anything about delivering a fluid at a location proximal to an occlusive device. In contrast to Applicant's claimed invention, Wolinsky et al. teach a device wherein a fluid passes through holes in an inflatable balloon. The balloon is positioned at the treatment site and the balloon is inflated for applying pressure to help force the fluid through the arterial wall.

Accordingly, Wolinsky et al. do not teach or suggest the unique combination of features recited by Claim 1. Applicant further submits that Wolinsky et al. do not teach or suggest the unique combination of features of dependent Claims 2 and 4. Therefore, Applicant respectfully requests that the rejections of Claims 1, 2 and 4 be withdrawn.

Applicant's independent Claim 36 recites a method for crossing an intravascular occlusion in a blood vessel. The method comprises delivering a hollow wire in a proximal to distal direction past the occlusion, and delivering fluids through a lumen in the hollow wire while crossing the occlusion. For reference, Applicant notes that Figures 9A and 9B of the present application show preferred embodiments of a hollow wire during use according to the method recited in Claim 36.

Wolinsky et al. fail to teach or suggest anything about delivering fluids through a lumen in a hollow wire to dissolve an occlusion. In contrast to Applicant's claimed method, Wolinsky et al. teach a device and method adapted for delivering fluid through the wall of a balloon while the balloon is inflated at a treatment site. Accordingly, the fluid is delivered while the balloon is stationary. The device taught by Wolinsky et al. is delivered to the treatment site after an angioplasty procedure has been performed and is configured for delivering a drug (e.g., heparin) to tissue at the treatment site. The balloon allows the drug to be delivered under sufficient pressure to cause the drug to penetrate the tissue.

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In summary, the device taught by Wolinsky et al. delivers a fluid through the wall of a balloon to tissue while the balloon is stationary at a treatment site. Furthermore, the fluid is delivered after an occlusion has been removed. Accordingly, Wolinsky et al. do not teach or suggest the combination of features recited by Claim 36. Furthermore, Wolinsky et al. do not teach or suggest the unique combination of features of dependent Claims 37-41.

In view of the foregoing amendment and remarks, Applicant respectfully submits that Claims 1, 2, 4 and 36-41 are patentably distinguishable over Wolinsky et al. Therefore, Applicant respectfully requests that the Examiner withdraw all claim rejections based on Wolinsky et al. under 35 U.S.C. § 102(b).

**Rejection of Claims 3, 5 and 6-8 under 35 U.S.C. § 103(a)**

The Examiner rejects Claims 3, 5 and 6-8 as being unpatentable over Wolinsky et al. in view of Spears (Claim 3), Nicholas (Claim 5) and Klein (Claims 6-8). However, as discussed above, Applicant has amended independent Claim 1 to recite a method that is neither taught nor suggested by Wolinsky et al. Furthermore, combining Wolinsky et al. with Spears, Nicholas, or Klein still fails to teach or suggest the method of Claim 1. Claims 3, 5 and 6-8 are dependent on amended Claim 1 and recite additional unique features of the claimed method. Accordingly, the combinations of references cited by the Examiner fail to disclose each and every element of Applicant's claimed invention and cannot be used to support the rejections of Claims 3, 5 and 6-8 under 35 U.S.C. § 103(a).

**Allowable Subject Matter**

Applicant appreciates the Examiner's determination that Claims 30 and 45 recite allowable subject matter. In the event that the base claims are not allowed, Applicant will rewrite Claims 30 and 45 in independent form to include all the limitations of the base claim and any intervening claims.

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**CONCLUSION**


In light of the foregoing amendments to the claims and the above remarks, Applicant earnestly believes that this application is now in condition for allowance, and such action is respectfully requested. Should the Examiner have any questions, the Examiner is encouraged to contact the attorney of record at the telephone number indicated below.

Respectfully submitted,

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